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EXAMINER

SAYALA, C

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UNITED STATES DEPARTMENT OF COMMERCE  
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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Paper No. 18

Serial Number: 08/946710  
Filing Date: 10/8/97  
Appellant(s): Staley A. Brod

Benjamin Aaron Adler

For Appellant

GROUP 1100

AUG 23 1997

MAILED

**EXAMINER'S ANSWER**

This is in response to appellant's brief on appeal filed  
6/23/99.

(1) Real Party in Interest.

A statement identifying the real party is contained in the  
brief.

(2) Related Appeals and Interferences.

A statement identifying the related appeals and interferences

which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of claims.

The statement of the status of claims contained in the brief is correct. Claims pending are 1-18.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of invention.

The summary of invention contained in the brief is correct.

(6) Issues.

The appellant's statement of the issues in the brief is correct.

(7) Grouping of claims.

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because although appellant has considered claims 1-18 to lie in four embodiments, claims 1-18 are not separately patentable as grouped since claims 1-7 include in their breadth each of the other

embodiments such that if claims 1-7 stand or fall so should claims 8-20. Indeed, the same may be said of claims 8-11, 12-15 and 16-18 wherein "decreasing the incidence of insulin-dependent diabetes mellitus" is inter-related to and concomitant with "reducing blood glucose levels" and "decreasing the onset of insulin-dependent diabetes mellitus in at-risk populations".

(8) Claims appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of record.

US 5019382	Cummins, Jr.	5/1991
US 5624895	Sobel	4/1997
WO 9420122	Sobel	9/1994
Shibutani et al.	Iyakuhin Kenkyu, Vol. 18(4), pages 571-582, 1987	
Gross et al.	Deutsche Medizinische Wochenschrift, vol. 111(36), pages 1351-5, 1986	
Giron et al.	J. Interferon Res., Vol. 8(6), pages 745-53, 1988.	

(10) New prior art.

No new prior art has been applied in this examiner's answer.

(11) Grounds of rejection.

1. The following is a quotation of the appropriate

1 paragraphs of 35 U.S.C. § 102 that form the basis for the  
rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -  
5 (b) the invention was patented or described in a printed publication in  
this or a foreign country or in public use or on sale in this country,  
more than one year prior to the date of application for patent in the  
United States."

9  
2. Claims 1-4, 6 are rejected under 35 U.S.C. § 102 (b) as  
being anticipated by Cummins, Jr. (U.S. Patent 5019382).

13 See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines  
12-26, col. 13, and the claims. Such disclosure meets the  
claims.

17 3. The following is a quotation of 35 U.S.C. 103 which forms  
the basis for all obviousness rejections set forth in this Office  
action:

21 A patent may not be obtained though the invention is not  
identically disclosed or described as set forth in section 102 of  
this title, if the differences between the subject matter sought  
to be patented and the prior art are such that the subject matter  
as a whole would have been obvious at the time the invention was  
25 made to a person having ordinary skill in the art to which said  
subject matter pertains. Patentability shall not be negated by  
the manner in which the invention was made.  
Subject matter developed by another person, which qualifies as  
prior art only under subsection (f) and (g) of section 102 of this  
29 title, shall not preclude patentability under this section where  
the subject matter and the claimed invention were, at the time the  
invention was made, owned by the same person or subject to an  
obligation of assignment to the same person.

33  
4. Claim 5 is rejected under 35 U.S.C. 103 as being  
unpatentable over Cummins, Jr. (U.S. Patent 5019382). The  
37 disclosure is the same as above as discussed for claim 1.  
The patent does not disclose an alternate day dosing.  
However, it does show that a daily dosage is possible, as a  
single dosage or as divided and administered in a multiple  
41 daily dose regimen. The reference also teaches a staggered

1 regimen of 1-3 days per week or month as an alternative to  
daily dosing. See col. 5, lines 50-55. With such a  
flexibility as taught by the reference, and since it is  
common knowledge in the art to employ such a regimen instead  
5 of continuous dosing, for a variety of reasons such as,  
toxicity, the condition of the patient, patient reaction and  
amelioration of the disease condition, etc., it would have  
been obvious to one of ordinary skill in the art to adopt an  
9 alternate day dosing and administer IFN as shown by Cummins  
for MS.

13 5. Claims 1-18 are rejected under 35 U.S.C. 103 as being  
unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view  
of Shibutani et al. (Iyaku hin Kenkyu, vol. 18(4), pp.  
571-82, 1987) and further in view of Sobel (abstract of WO  
9420122 or US Patent 5624895).

17 The disclosure for the patent is as discussed above.  
The whole range of dosages claimed by the instant invention  
is not shown. However, the Shibutani abstract indicates  
that IFN toxicity studies with rats showed that it was  
21 tolerated well. Therefore it would have been obvious to one  
of ordinary skill in the art to administer dosages higher  
than that shown in the patent with the reasonable  
expectation that such doses would not produce toxicity  
25 side-effects in humans. It would also have been obvious to  
employ such an alternate day dose regimen instead of  
continuous dosing, for a variety of reasons such as,  
toxicity, the condition of the patient, patient reaction and  
amelioration of the disease condition, etc. Note that  
29 although Cummins discloses interferon for autoimmune  
diseases which includes the diabetes claimed herein, the  
reference does not expressly state that the disease

1 condition is diabetes. However Sobel shows the use  
interferon for diabetes and that diabetes was known in the  
art as an autoimmune disease at the time the invention was  
made. See col. 8, line 63 to col. 9, line 5 and claims 11-  
5 12 and 18.

6. A rejection based on double patenting of the "same  
invention" type finds its support in the language of 35  
9 U.S.C. 101 which states that "whoever invents or discovers  
any new and useful process ... may obtain a patent therefor  
..." (Emphasis added). Thus, the term "same invention," in  
this context, means an invention drawn to identical subject  
13 matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894);  
*In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In*  
*re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

17 A statutory type (35 U.S.C. 101) double patenting  
rejection can be overcome by canceling or amending the  
conflicting claims so they are no longer coextensive in  
scope. The filing of a terminal disclaimer cannot overcome  
21 a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1-7 are provisionally rejected under 35 U.S.C.  
\$ 101 as claiming the same invention as that of claims 1-7  
25 of copending application Serial No. 08/631470. This is a  
*provisional* double patenting rejection since the conflicting  
claims have not in fact been patented.

29 8. Claims 1-18 are provisionally rejected under 35 U.S.C.  
\$ 101 as claiming the same invention as that of claims 1-18  
of copending application Serial No. 08/844731. This is a  
33 *provisional* double patenting rejection since the conflicting  
claims have not in fact been patented.

37 9. Claims 8-18 are provisionally rejected under the  
judicially created doctrine of obviousness-type double

1 patenting as being unpatentable over claims 1-18 of  
copenending application Serial No. 08/631470 in view of the  
abstracts of WO 94/20122, Gross et al. and Giron et al.  
Although the conflicting claims are not identical, they are  
5 not patentably distinct from each other because the subject  
matter of these claims would have been obvious in view of  
the abstracts that show that it was already known in the art  
at the time the invention was made that interferon prevented  
9 the onset of diabetes. [Filing date accorded to the claims  
8, 12 and 16 reciting diabetes mellitus (prevention, etc.) is  
4/15/96].

This is a *provisional* obviousness-type double patenting  
13 rejection because the conflicting claims have not in fact  
been patented.

10. The obviousness-type double patenting rejection is a  
17 judicially established doctrine based upon public policy and  
is primarily intended to prevent prolongation of the patent  
term by prohibiting claims in a second patent not patentably  
distinct from claims in a first patent. *In re Vogel*, 164  
21 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in  
compliance with 37 C.F.R. § 1.321(b) would overcome an  
actual or provisional rejection on this ground provided the  
conflicting application or patent is shown to be commonly  
25 owned with this application. See 37 C.F.R. § 1.78(d).

#### (13) Response to argument.

29 On page 9 of the brief, appellant has criticized the  
Cummins reference for showing only one anecdotal report and  
being "extremely limited" (see declaration submitted). He  
33 argues that "this limited clinical data" cannot be  
considered enabling and therefore should be held  
"incredible" and therefore non-anticipatory. See page 10 of  
the brief. Enablement requires that the specification teach



1 those in the art to make and use the invention without  
"undue experimentation". *In re Wands*, 858 F.2d 731, 737, 8  
USPQ2d 140, 1404 (Fed. Cir. 1988). The specification and  
5 data therein is considered to be adequate to provide the  
skilled worker enough to practice the invention without  
"undue experimentation". A patent cannot be called "non-  
enabling" because appellant has produced data from 27  
patients and 18 controls versus the one example in the  
9 patent used. See MPEP §2164.02.

As for amounts discussed at page 17 of the Brief, the  
claims rejected under 35 USC 102 do not contain the  
limitation that appellant has based his arguments on (SEE  
13 page 7 of the Brief) and as for claim 10 or 14 note that the  
claim is rendered obvious by Cummins Jr. showing 5 I.U./kg  
which overlaps with the end point of the claimed range.

Appellant's discussion of Cummins' mode of  
17 administration at pages 14-16 of the response is also not  
persuasive. There is nothing clearly distinguishable  
between "orally administering...such that the ...interferon  
is ingested after oral administration" (see claim 1) and  
21 Cummins' mode. Appellant has argued at page 15 that in his  
specification the interferon was fed through a needle  
inserted into the stomach and there was no oral or  
pharyngeal contact. There are no such limitations in the  
25 claims, however, and the relevance of this argument in view  
of the instantly claimed limitations and claim recitation is  
not clear. Appellant cannot rely on the specification to  
impart to the claims limitations not recited therein. Such  
29 a reliance is ineffective to define over the prior art. *In*  
*re Lundberg*, 244 F2d 543, 113 USPQ 530 (CCPA 1957), *In re*  
*Winkhaus*, 188 USPQ 129 (CCPA 1975). See also *In re Hyson*,  
172 USPQ 399, *In re Tiffin*, 171 USPQ 294, *In re Lindner*, 173

1 USPQ 356: It is well established that the objective evidence  
of nonobviousness must be commensurate in scope with the  
claims.

5 Appellant also argues that there was only "brief"  
exposure of interferon to the oral mucosa in his method.  
Pages 13-14 of the Brief. The claims herein do not recite  
anything to this end and there is no recitation or  
disclosure to show such a "brief" exposure only. Appellant  
9 states on page 14, last 2 sentences that the claims state  
that the interferon is to be ingested upon oral  
administration and that the interferon is only in contact  
with the oral mucosa during the swallowing process, which  
13 takes a fairly brief period of time. It is obvious to the  
artisan from the reference that even in Cummin's mode a  
small or considerable amount of interferon will be  
eventually ingested as a normal course of events. The  
17 feature of mode of administration urged by appellant as  
distinguishing enough to be the basis of patentability, is  
not clear and convincing or of patentable moment, based on  
the disclosure and claim language.

21 Appellant's pointing out col. 5, lines 50-55 (see page  
19 of the Brief) of Cummins is also unpersuasive. The  
patent clearly teaches "Daily dosage of interferon....as a  
single dosage". Appellant argues that although the  
25 reference teaches that a regimen of 1-3 days per week or  
month is discussed, that this is only disclosed as a less  
preferred embodiment (page 20 of the Brief). Nowhere in any  
statute is there a requirement that only the preferred  
29 embodiment of the reference should be considered a teaching  
and the rest of the reference be ignored. See *In re Uhlig*,  
153 USPQ 460, *In re Mills*, 176 USPQ 196 (CCPA 1972)

Both the traversal of the rejection over claim 5 and

1 the declaration have been carefully reviewed and considered  
and the above discussions apply here too.

Appellant's traversal of the rejection of claims 1-18  
at page 20 is also in error. Test for combining references  
5 is not what individual references themselves suggest but  
what the combination of disclosures taken as a whole would  
suggest to one of ordinary skill in the art. *In re*  
*McLaughlin*, 170 USPQ 209 (CCPA 1970). Appellant has  
9 improperly criticized the references individually where the  
rejection is based upon the combined teachings of the  
references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231  
USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413,  
13 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be  
established by attacking references taken individually when  
rejection is based on a combination of references. *Ex parte*  
*Campbell* 172 USPQ 91 (BPA&I 1971). Note that Shibutani's  
17 abstract is used to show toxicity studies only and the  
motivation it provides to the artisan to do what appellant  
has done. Sobel shows the use interferon for diabetes and  
that diabetes was known in the art as an autoimmune disease  
21 at the time the invention was made. Similarly, Gross et al  
and Giron et al references were used only to show that the  
art was well aware that interferon could be administered to  
diabetic subjects without side-effects due to toxicity and  
25 that interferon prevented diabetes. Such secondary  
references provide motivation when taken together with  
Cummins Jr.

Appellant's response to the double patenting and  
29 obviousness type double patenting rejections have been noted  
at pages 5 and 26 of the Brief and those rejections are  
being maintained as proper and valid. Appellant's response  
to the Sequence listing requirement has been noted, although

1 it is recognized that this is not appealable subject matter.  
The sequence listing has been approved and entered.

5 For the above reasons, it is believed that the  
rejections should be sustained.

Respectfully submitted,

9  
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